Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

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Chapter 13

November 25, 1991

1. Transmitted is a new chapter to the Department of Veterans Affairs, Veterans Health Administration Manual M-3, "Research and Development in Medicine," Part I, "General," Chapter 13, "Cooperative Research and Development Agreements."

2. The principal purpose is the addition of Chapter 13, "Cooperative Research and Development Agreements" to the existing manual. This chapter defines CRADA (Cooperative Research and Development Agreement), it's history and scope. Appendix 13A is a sample of "A Model CRADA, and Appendix 13B, is a sample of "A Model License Agreement."

3. Filing Instructions

Remove Pages	Insert Pages
iii through viii	iii through viii
	13-i through 13B-8

4. RESCISSIONS: VHA Circular 10-89-131, dated December 12, 1989, and Supplement No. 1 dated April 16, 1990; and VHA Circular 10-90-115, dated September 6, 1990.

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Chief Medical Director

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FOREWORD

VA Department of Medicine and Surgery Manual M-3, "Research and Development in Medicine," Part I, "General," April 27, 1982, has been completely rewritten to incorporate all policy and procedural changes arid additions in the administration of research and development since that date. Parts II, III, and IV have also been completely rewritten to provide a convenient, readable set of documents for clear communication and effective administration of research and development. Similar reissuances are planned at 2-year intervals in the future.

The Research and Development Manual covers all three Research and Development Services and is organized as follows:

Part I General
Part II ..... Medical Research Program
Part III ..... Health Services Research and Development Program
Part IV ..... Rehabilitation Research and Development Program

The provisions of this manual apply to all medical, rehabilitation and health services research conducted in VA medical centers, both locally and centrally reviewed.

RESCISSIONS

The following material is rescinded:

1. COMPLETE RESCISSIONS

a. Manuals

M-3, part I, chapter 12, dated January 31, 1989

b. Interim Issues

II 10-81-44

c. Circulars

10-84-75 (Research General Post Funds)
10-87-27 and Supplement No. 1
10-87-53 and Supplement No. 1
10-87-110 and Supplement No. 1
10-89-131 and Supplement No. 1
10-90-115

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CHAPTER 13. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

RESCISSIONS

The following material is rescinded:

1. COMPLETE RESCISSIONS

Circulars

10-89-131 and Supplement No. 1
10-90-115

CHAPTER 13. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

13.01 INTRODUCTION

The FTTA (Federal Technology Transfer Act) of 1986, Public Law 99-502, codified at 15 U.S.C. 3710 et seq. authorized the CRADA (Cooperative Research and Development Agreement) as a new mechanism to encourage the transfer of the results of Federal research and development to the private sector. This chapter:

a. Defines the CRADA;

b. Provides a model CRADA and an accompanying licensing agreement;

c. Describes the legal authorization for CRADAs;

d. Describes the governmental purposes to be achieved by these agreements and the possible benefits to Federal scientists;

e. Presents criteria for the selection of non-Federal collaborators in CRADAs;

f. Summarizes policies and procedures for negotiating and entering into CRADAs and for handling funds associated with CRADAs; and

g. Provides guidance for dealing with possible problems of conflict of interest.

13.02 DEFINITION OF A CRADA

A CRADA is an agreement between VA (Department of Veterans Affairs) and one or more non-Federal parties under which VA "laboratory directors" (defined herein as medical center directors) may accept, retain and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties, and in exchange may provide personnel, services, facilities, equipment, or other resources, but not funds toward the conduct of specified research and development efforts which are consistent with VA's mission. (See 15 U.S.C. 3710a(d)(1).) The laboratory director may also, in advance, grant licenses or assignments to collaborating parties for any inventions made by a Federal employee under such agreements; and also in advance, may waive Federal government ownership to any joint inventions made under such agreements. However, a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world by or on behalf of the government must be retained. (See 15 U.S.C. 3710a(b)(2) and (3).) In such cases where it is determined to grant any of the rights in advance, they shall be granted directly to the collaborating party.

13.03 A MODEL CRADA

a. The agreement provided in Appendix 13A is intended as a model. However, justification shall be provided for any significant change from the model

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agreement to expedite the review process in the OGC (Office of General Counsel). Changes or additions should be indicated by underlining, and deletions should be marked through for easy identification.

b. The information contained in the brackets in the model agreement is intended as an example; it should be changed to reflect specific information pertaining to each agreement.

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c. Paragraphs 6.2 through 6.5 of the model CRADA concern the disposition of patent rights to inventions. The VA laboratory director, on behalf of the government must always retain a nonexclusive, irrevocable, paid up license to subject inventions that are assigned to private entities under those provisions. The amount of royalties to be retained under paragraph 6.7 on subject inventions assigned to private entities is discretionary.

d. Attached to the model agreement is a blank page entitled Appendix A to the agreement, CRADA, Statement of Work. The Statement of Work should contain a detailed explanation of the research work to be performed under the agreement.

e. The license agreement presented in Appendix B is to be used for any inventions for which VA has ownership rights when a collaborating party is interested in further developing such an invention through a CRADA. The license agreement may also be used to license inventions of other parties when a collaborating party under CRADA has assigned to VA the rights to a subject invention (see par. 6.5 of app. 13A) and VA has determined to file for patent protection and is seeking to market the subject invention.

f. Each CRADA must be accompanied by an agreement between the medical center and the investigator under which the investigator shall receive at least 15 percent of the royalty income derived from subject inventions, not to exceed $100,000 per year, in accord with Section 7 of FTTA (15 U.S.C. 3710c (a) (1) (B).

g. Resolution of any disputes under the CRADA, as specified in paragraph 10.2 of the model agreement, shall be referred to arbitration in accordance with the arbitration Rules of the American Arbitration Association then in effect, if the parties are unable to resolve the dispute.

13.04 LEGAL AUTHORITY FOR CRADAs

a. Statutory Authority. The statutory basis for Federal agencies entering into CRADAs is provided by FTTA and Executive Order 12591 (April 10, 1987) entitled, Facilitating Access to Science and Technology.

b. Regulatory Authority. Under 38 CFR (Code of Federal Regulations) 2.83 authority has been delegated to the directors of VA medical centers, as "laboratory directors" under FTTA, within existing resources, to enter into CRADAs or license agreements as described by Section 2 of FTTA (15 U.S.C. 3710a (a)(1) and (2)) between the laboratory and the private sector. Although laboratory directors have authority to enter into CRADAs, they shall obtain prior approval for these agreements from OGC (024). A draft (unsigned) copy should be sent initially. Once General Counsel has reviewed the draft and notified the laboratory director of any necessary changes, a final agreement may then be expected and forwarded for final approval. The OGC has 30 days from the receipt of the final agreement to modify or reject it (see par. 8.1 of app. 13A); however, such modification or rejection will be accompanied by a written explanation. (Submittal of a draft agreement will expedite the final review process and will largely diminish the need to modify or reject final agreements).

c. VA Policy. VA fully supports the goal of the FTTA and Excutive Order 12591 and specifically encourages the development of cooperative research and development agreements.

13.05 ADVANTAGES OF CRADAs

a. General. The ultimate objective of the provisions of the FTTA, including the

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authorization of CRADAs, is to improve the economic, environmental, and social well being of the United States by stimulating the utilization of federally funded research and development. This objective is to be accomplished by encouraging increased interactions between the federal government, universities, foundations (profit and nonprofit) and industry, thereby facilitating the transfer of federal technology from federal laboratories to the private sector for further development and commericalization. This interaction is to be stimulated by the sharing of resources and of rewards resulting from the creation of intellectual property among the participating organizations and their employees.

b. Advantages for VA Investigators. CRADAs can provide three major benefits for VA investigators:

(1) Their research can be supported completely or partially by resources provided by the non-federal collaborator.

(2) At least 15 percent of any royalties or other income received by VA on account of any invention under a CRADA shall be paid to the inventor (not to exceed $100,000 per year) (15 U.S.C. 3710c (a)(1)(A).

(3) VA employees or former employees may be permitted to participate in the commercialization of inventions they make or made while VA employees.

c. Advantages for VA Research Program (local and national). VA has the advantage of free use of the invention for all time, and/or VA has the advantage of royalty income. At least 15 percent of any royalty income must go to the inventor, and the balance of the VA share goes to the national R&D (Research and Development) program; however, the majority of this balance will be transferred back to the laboratory in which the invention was made, thereby enabling further research.

d. Advantages for Non-Federal Collaborators. The primary incentive for the non-federal collaborator to enter into CRADAs is the access to federally developed know-how and technology, with the potential for profit making that such access brings.

13.06 CRITERIA FOR SELECTING NON-FEDERAL COLLABORATORS

In negotiating CRADAs, laboratory directors shall give preference to:

(a) Business units located in the United States which agree that products embodying inventions made under CRADAs will be manufactured substantially in the United States, and

(b) Small businesses and consortia involving small business firms. Laboratory directors must follow the requirement of 15 U.S.C. 3710a(c)(4)(B) pertaining to the preference for business units located in the United States.

13.07 PROCEDURES FOR NEGOTIATING AND ENTERING INTO A CRADA

a. Investigator identifies potential collaborator.

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b. Investigator informs potential collaborator of statutory requirements for CRADAs by presenting a copy of model CRADA when discussion of collaborative agreement first begins.

c. Investigator informs ACOS (Assistant Chief of Staff)/R&D or Coordinator/R&D of possibility of developing a CRADA.

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d. Investigator and collaborator draft a CRADA, using model CRADA presented in Appendix 13A of this chapter as a guide.

e. If applicable, the investigator and the collaborator draft a license agreement following the model license agreement in Appendix 13B (see par. 13.03e).

f. ACOS/R&D or Coordinator/R&D assures that the research to be performed under the CRADA has been or will be approved by the R&D Committee and appropriate subcommittee.

g. ACOS/R&D or Coordinator/R&D requests laboratory director (medical center director) to submit draft CRADA to OGC for review and approval.

h. Laboratory director sends CRADA (and license agreement if applicable) to OGC (024). (See paragraph 13.03a.)

i. OGC reviews draft CRADA and associated agreements.

j. OGC sends draft CRADA to Office of R&D (12/3) for evaluation of consistency of proposed research with VA research mission.

k. Office of R&D reviews draft CRADA for consistency with VA research mission.

l. OGC writes to laboratory director indicating either approval of draft CRADA or recommending changes in draft CRADA.

m. Laboratory director and collaborator execute final CRADA and, if applicable, license agreement.

n. Laboratory director distributes the executed CRADA and copies thereof as follows:

(1) Original to master file in laboratory director's office;

(2) One original signed copy to collaborator;

(3) One original signed copy to the Office of R&D (12/3), VA Central Office; and

(4) Reproduced copies to the principal investigator and other VA employees performing research under the CRADA.

o. Office of R&D maintains a central file of CRADAs.

13.08 PROCEDURES FOR HANDLING FUNDS ASSOCIATED WITH CRADAs

a. Two classes of funds are associated with CRADA's:

(1) Funds initially contributed by the non-Federal party as part of the agreement itself.

(2) Funds received from marketing and licensing intellectual property resulting from the collaborative research.

b. Funds initially contributed by the non-Federal party will be deposited to budget clearing account 36F3875. When the laboratory (medical center) performs the work related to a CRADA, the laboratory director will establish receivable reimbursements,

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notify VA Central Office of reimbursement earned and transfer appropriate amount of funds from the suspense account to the research appropriation as a reimbursement. VA Central Office will increase research obligation authority by the amount of reimbursement collected.

c. Funds received from marketing and licensing intellectual property should be sent to VA Central Office (Finance Office). VA Central Office will disburse the inventor's share of royalty income to the inventor, and will distribute the remainder to medical center laboratories, with the majority being returned to the laboratory at which the invention occurred, as specified in 15 U.S.C. 3710c (a) (1)(A)(i).

d. Income returned by VA Central Office to the laboratory shall be deposited into 36 / 161, VA Medical and Prosthetic Research, as a reimbursement to the appropriation, and may be used for:

(1) Paying expenses incidental to administering and licensing other inventions;

(2) Rewarding laboratory employees;

(3) Furthering scientific exchange among Government-operated laboratories; and

(4) Employee education and training which furthers the laboratory's research and development goals.

e. Any royalty income or other income generated from a CRADA which is not used or obligated at the end of the fiscal year following the fiscal year in which it was received, shall be paid to the U.S. Treasury.

f. Laboratory directors may transfer funds received under a CRADA for the conduct of its research to a nonprofit research corporation for administration.

g. Royalties and other income from licensing or assignment of inventions are not received for the conduct of VA research and may not be transferred to and administered by a nonprofit research corporation.

13.09 INVENTION MANAGEMENT SERVICES

Royalty income may be used for the payment of expenses incidental to the administration and licensing of inventions, e.g., by contracting for the services of a private sector firm.

a. However, any agreement intended to cover services of other agencies, persons, or organizations for invention management and licensing services as permitted by 15 U.S.C. 3710c(a)(1)(B)(i) and (a)(4) shall be sent to the OGC for review and approval prior to their execution and implementation.

b. However, as intended by 15 U.S.C. 3710(a)(1)(B), invention identification and evaluation and the filing of patent applications on those inventions retained are the responsibility of the laboratory directors or other persons designated by the laboratory directors without further review or approval.

c. Such invention identification and evaluation and the filing of patent applications may be undertaken through the use of distributed royalties or other income, as part of a cooperative or license agreement or from other available resources.

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13.10 CONFLICT OF INTEREST CONSIDERATIONS

The basic VA requirements regarding employee conduct standards in general and the avoidance of conflict of interest in particular is contained in 38 CFR 0.735. In order to comply with Section 2 of the FTTA, any potential conflict of interest arising during the negotiation of a CRADA or in the commercialization of inventions resulting from a CRADA should be immediately discussed with the OGC (023).

13.11 NONPROCUREMENT DEBARMENT AND SUSPENSION

Prospective participants (non-Federal) in CRADAs shall submit the certification required by 38 CFR 44.510 as a basis for VA's deciding that these prospective participants should not be subject to VA's nonprocurement debarment and suspension regulations promulgated at 38 CFR 44.100 through .630.

13.12 REFERENCES

a. 15 U.S.C. 3710

b. 38 CFR 2.83

c. 38 CFR 44.100 through .630

PROPOSED MODEL COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

INTRODUCTION

This proposed Model CRADA (Cooperative Research and Development Agreement) is presented in accordance with Section 5 of the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710(g)(1)(B)). In providing this model agreement, our intention is to furnish advice and assistance for a generic model from which parties can add to or subtract from as they think appropriate for their particular situation. The definition of cooperative agreement in the Act (15 U.S.C. 3710a(d)) excludes a procurement contract, grant, or cooperative agreement. Consequently, the CRADA does not include all the terms and conditions used in these legal instruments or the required clauses in the FAR (Federal Acquisition Regulations). The clauses in brackets ([ ]) should be changed to refer to parties and matters relative to each agreement. The OGC (Office of General Counsel) is available to assist you in any way relating to this matter.

MODEL COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This CRADA (Cooperative Research and Development Agreement), dated as of _____ _____, is entered into by and between the [for example: ABX Company, Inc., a New York Corporation], hereinafter referred to as [the Company] and the VA Medical Center, [location], a laboratory of Department of Veterans Affairs, hereinafter referred to as VA.

A. Whereas, the Congress in enacting the Federal Technology Transfer Act of 1986, Public Law No. 99-502, October 20, 1986, has found that Federal laboratories' developments should be made accessible to private industry, State and local governments, and has declared that one of the purposes of such Act is to improve the economic, environmental and social well being of the United States by stimulating the utilization of Federally-funded technology developments by such parties;

B. Whereas, the Federal Technology Transfer Act of 1986 among other technology transfer improvements, has provided each Federal agency with the authority to permit the directors of Government-operated Federal laboratories to enter into CRADA with Federal or non-Federal entities, including private firms and organizations for the purposes of providing to or obtaining from, collaborating parties, personnel, services, property, facilities, equipment or other resources (including funds except that funds may only be obtained from collaborating parties and may not be provided to such collaborating parties) toward the conduct of specified research and development efforts which may include the disposition of patent rights in the inventions which may result from such collaboration;

C. Whereas, [the Company] has performed substantial research and development with respect to [for example, radionuclides from rare earth elements with

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cancer therapy potential and has substantial expertise in the generation and characterization of monoclonal antibodies and their in-vivo binding abilities, hereinafter referred to as "the Technology"];

D. Whereas, VA possesses [for example, certain advanced scientific skills, facilities, special equipment, information, computer software, and know-how pertaining to the Technology];

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E. Whereas, VA desires to pursue the development of the Technology with the objective of developing [for example, cancer therapeutic reagents consisting of specific monoclonal antibodies coupled to specific radionuclides with cell killing potential];

F. Whereas, [the Company] is interested in the further development of the Technology and its utilization by private and public [for example, medical institutions];

G. Whereas, [the Company] desires to provide resources for VA's further development of the Technology and subsequently, upon the successful completion of development, carry out a plan for marketing of the [for example, reagents leading to the wide-spread commercial availability of such reagents];

H. Whereas, VA views its collaboration with [the Company] to develop the Technology and the commitment of [the Company] to undertake its marketing plan to be in the furtherance of the public interest.

Now, therefore, the parties hereto agree as follows:

ARTICLE I. DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings and such meanings should be equally applicable to both the singular and plural forms of the terms defined:

1.1 CRADA (Cooperative Research and Development Agreement) means this agreement as used herein.

1.2 Invention means any invention or discovery which is or may be patentable under Title 35 of the United States Code or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 7321 et seq.).

1.3 Made in relation to any invention means the conception or first actual reduction to practice of such invention.

1.4 Proprietary Information means information which embodies trade secrets developed at private expense or which is confidential business or financial information provided that such information:

a. Is not generally known or available from other sources without obligations concerning its confidentiality;

b. Has not been made available by the owners to others without obligation concerning its confidentiality; and

c. Is not already available to the Government with out obligation concerning its confidentiality.

1.5 Subject Data means all recorded information first produced in the performance of this Agreement.

1.6 Subject Invention means any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

1.7 Laboratory Director means the director of the VA medical center that is a party to this Agreement.

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ARTICLE II. COOPERATIVE RESEARCH

2.1 Statement of Work.

a. Cooperative research performed under this Agreement shall be performed in accordance with the SOW (Statement of Work) attached hereto as Appendix A to CRADA.

b. VA agrees to perform the cooperative research and to utilize such personnel, resources, facilities, equipment, skills, know-how and information as it considers necessary, consistent with its own policies, missions and requirements. [The Company] agrees to provide [for example, personnel, resources, etc., and/or funds] as set forth in Article 4].

2.2 Review of Work. Periodic conferences shall be held between VA and [the Company] personnel for the purpose of reviewing the progress of work; however, VA shall have exclusive control and supervision over the conduct of all cooperative research. It is understood that the nature of this cooperative research is such that completion within the period of performance specified, or within the limits of financial support allocated, cannot be guaranteed. Accordingly, it is agreed that all cooperative research is to be performed on a "best efforts" basis.

2.3 Principal Investigation. The work will be performed under the supervision of Dr. _____, who as principal investigator has the responsibility for the scientific and technical conduct of this project.

2.4 Scope Change. If at any time VA determines that the research data justifies a substantial change in the direction of the work, VA shall promptly notify [the Company] and the parties shall make a good faith effort to agree on any necessary change to the SOW.

ARTICLE III. REPORTS

3.1 Quarterly Reports. Commencing 3 months after the effective date, VA shall submit quarterly written reports to [the Company] during the term of this Agreement on the progress of its work and the results being obtained and shall make available to [the Company] to the extent reasonably requested, other project information in sufficient detail to explain the progress of the work.

3.2 Final Reports. VA shall submit a final report of its results within [for example, 4 months] after completing the SOW.

ARTICLE IV. FINANCIAL OBLIGATION

4.1 Advance Payment. The performance of research by VA under this Agreement is conditioned on the advance payment by [the Company] of VA's full cost for the performance of such research. (Use this clause only if Agency desires advance payment.)

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4.2 Deposit Account. [The Company] shall pay $[ ] to VA for the performance of the research specified by Article 2.

a. Such funds shall be deposited in VA Account No. [_____], as follows:

$[ ] to be deposited upon the execution of this Agreement;

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$[ ] to be deposited [30 days prior to the beginning of the second budget period];

$[ ] to be deposited [30 days prior to the beginning of the third budget period]; and

$[ ] to be deposited [30 days prior to the beginning of the fourth budget period].

b. VA shall not be obligated to perform any of the research specified herein or to take any other action required by this Agreement if the agreed-to funds are not deposited as required by this Article.

4.3 Insufficient and Excess Funds. VA shall not be required to continue its research and development activities under this Agreement if the funds provided by [the Company] are insufficient to cover VA's full cost for such continued activities. Funds not expended by VA shall be returned to [the Company] upon VA's submission of a final fiscal report to [the Company].

4.4 Accounting Records. VA shall maintain separate and distinct current accounts, records, and other evidence supporting all its expenditures under this Agreement. VA shall provide [the Company] a report within _____ months after completing the SOW or ending its research activities under this Agreement. These accounts and records of VA shall be available for reasonable inspection and copying by [the Company] and its authorized representative.

ARTICLE V. TITLE TO PROPERTY

5.1 Capital Equipment

a. All capital equipment developed or acquired under this Agreement shall be the property of VA, except that title to the following items of capital equipment provided to VA by [the Company] or acquired by VA with funds supplied by [the Company] shall remain or vest in [the Company]: [list equipment]

b. Upon completion of the research by VA, [the Company] shall be responsible for all costs attendant to the maintenance, removal, storage and shipping of identified capital equipment to [the Company].

ARTICLE VI. PATENT RIGHTS

6.1 Reporting. VA shall promptly report to [the Company] each Subject Invention reported to VA by its employees. [The Company] shall promptly report to VA each Subject Invention reported to [the Company] by any of its employees.

6.2 [Company] Employee Inventions. VA, on behalf of the U.S. Government, agrees that [the Company] shall have title to any Subject Invention made solely by [Company] employees. However, VA shall retain, as consideration for its contribution towards development of a subject invention, a nonexclusive,

nontransferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world by or on behalf of the Government.

6.3. VA Employee Inventions. VA shall have the initial option of retaining title to any Subject Invention made solely by a VA employee. VA shall notify [the Company]

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promptly upon making this election and agrees to timely file patent applications on such Subject Invention at its own expense, except as provided in paragraph 6.5. VA agrees to grant to [the Company] on its employee Subject Inventions an exclusive license in the patents covering a Subject Invention. Should VA elect not to retain title to a Subject Invention under this paragraph, it agrees to assign right, title, and interest to [the Company] subject to the reservation in the Government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world by or on behalf of the Government.

6.4 Joint Inventions. [The Company] shall have the initial option to retain title to each Subject Invention made jointly by [the Company] and one or more VA employees. In the event that [the Company] informs VA that it elects to retain title to such joint Subject Invention, VA agrees to assign whatever right, title and interest VA has in and to such joint Subject Invention, subject to reservation of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world by or on behalf of Government.

6.5 Filing of Patent Applications. If either party elects not to file a patent application on a Subject Invention, it so must advise the other party within 90 days from the date it reports the Subject Invention. Thereafter, the other party may elect to file patent applications on such Subject Invention and the party not seeking a patent agrees to assign its right, title and interest in such Subject Invention and cooperate in the preparation and filing of patent applications thereon. In the event neither of the parties to this agreement elects to file a patent application on a Subject Invention, either or both (if a joint invention) may release the right to file to the inventor(s) with a nonexclusive, nontransferable, irrevocable, paid-up license in each party.

6.6 Patent Expenses. The expenses attendant to the filing of patent applications as specified in paragraph 6.5, shall be borne by the party filing the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office.

6.7 Payments of Royalties. As consideration for an assignment of rights to [the Company] as provided in paragraphs 6.3 and 6.4, [the Company] shall pay a running royalty to VA in an amount equal to [for example, 3 percent of the net selling price]. Should [the Company] determine that it does not intend to incorporate the invention(s) covered by the claims of a patent involving a Subject Invention assigned to it by VA under the terms of this Agreement into a licensed product, [the Company] shall assign or reassign to VA ownership rights to such invention and any such patent as [the Company] had in such invention. The provisions of this article shall survive the termination of this Agreement. [Additional provisions concerning payment of royalties should be included here, for example: Anything to the contrary notwithstanding, running royalty payments with respect to all sales, transfers, or consignments of licensed products made by [the Company] to an affiliate or purchaser or party that does not deal at arms-length with [the Company] shall be computed on an amount equal

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to the price at which [the Company] at the time of such sales would invoice or similar licensed products to purchasers dealing at arms-length with [the Company], provided, however, that such royalty payments for such sales, transfers or consignments shall not become due and payable until sale or transfer to parties dealing at arms-length with [the Company] and its affiliates.]

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ARTICLE VII. DATA AND PUBLICATION

7.1 Rights. Subject to the provisions of paragraph 7.3, Subject Data which are required to be delivered to [the Company] under this Agreement shall be the property of [the Company]. [The Company] shall, upon request, have the right to review all Subject Data first produced under this Agreement which have not been delivered to [the Company], except to the extent that such Subject Data is subject to a claim of confidence or privilege by the third party.

7.2 Proprietary Information. [The Company] shall place a Proprietary notice on all information it delivers to VA under this Agreement which it asserts is proprietary. VA agrees that any information designated as proprietary which is furnished by [the Company] to VA under this agreement, or in contemplation of this agreement, shall be used by VA only for the purpose of carrying out this agreement. Information designated as proprietary shall not be disclosed, copied, reproduced or otherwise made available in any form whatsoever to any other person, firm, corporation, partnership, association or other entity without the consent of [the Company] except as such information may be subject to disclosure under the FOIA (Freedom of Information Act) (5 U.S.C. 552). VA agrees to use its best efforts to protect information designated as proprietary from unauthorized disclosure. [The Company] agrees that VA is not liable for the disclosure of information designated as proprietary which, after notice to and consultation with [the Company], VA determines may not lawfully be withheld or which a court of competent jurisdiction requires disclosed.

7.3 Release Restrictions. VA shall have the right to use all Subject Data for any governmental purpose, but shall not release such Subject Data publicly except:

a. VA, when reporting on the results of sponsored research, may publish Subject Data, subject to the provisions of paragraph 7.4, and provided [the Company] is given a 90-day opportunity to review the manuscript and provide suggestions before publication; and

b. VA may release such Subject Data where such release is required pursuant to a request under FOIA (5 U.S.C. 552); provided, however, and consistent with FOIA, such data shall not be released to the public if a patent application is to be filed (35 U.S.C. 205) until the party having the right to file has had a reasonable time to file.

7.4 Publication. VA and [the Company] agree to confer and consult prior to the publication of Subject Data to assure that no Proprietary Information is released and that patent rights are not jeopardized. Prior to submitting a manuscript for review which contains the results of the research under this Agreement, or prior to publication. If no such review is made, each party shall be offered an ample opportunity to review such proposed publication and to file patent applications in a timely manner, if it is so entitled under this Agreement.

ARTICLE VIII. REPRESENTATIONS AND WARRANTIES

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8.1 Representations and Warranties of VA. VA hereby represents and warrants to [the Company] as follows:

8.1.1 Organization. The VA medical center [location] is a Federal laboratory of VA, is wholly owned by the Government of the United States, and a substantial purpose of the medical center is the performance of research, development, or engineering by employees

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of said Government;

8.1.2 Mission. The performance of the activities specified by this Agreement are consistent with the mission of VA.

8.1.3 Authority. The VA official executing this Agreement has the requisite authority to do so. The OGC (024), VA Central Office, retains the right to modify or reject this Agreement within 30 days of receipt of the Agreement. Any rejection or modification will be accompanied by a written explanation to the laboratory head and [the Company].

8.1.4 Statutory Compliance. The laboratory head, prior to entering into this Agreement, has given special consideration to entering into CRADAs with small business firms and consortia involving small business firms.

8.2 Representations and Warranties of [the Company]. [The Company] hereby represents and warrants to VA as follows:

8.2.1 Corporate Organization. [The Company], as of the date hereof, is a corporation duly organized, validly existing and in good standing under the laws of the State of [for example, New York], and (if applicable) is a wholly owned subsidiary of [for example, Y, Inc., a Delaware corporation].

8.2.2 Power and Authority. [The Company] has the requisite power and authority to enter into this Agreement and to perform according to the terms thereof.

8.2.3 Due Authorization. [The Board of Directors and stockholders] of [the Company] have taken all action required to be taken by law, [the Company's] Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of this Agreement.

8.2.4 No Violation. The execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under any material agreement binding on [the Company] or any valid order of any court, or any regulatory agency or other body having authority to which [the Company] is subject.

ARTICLE IX. TERMINATION

9.1 Termination by Mutual Consent. [The Company] and VA may elect to terminate this Agreement, or portions thereof, at any time by mutual consent in writing. In such event the parties shall specify the disposition of all property, patents and other results of work accomplished or in progress, arising from or performed under this Agreement. Upon a termination by mutual consent which has been reduced to writing, VA shall not make any new commitments and shall, to the extent feasible, cancel all outstanding commitments that relate to this Agreement or portions thereof mutually terminated by the termination date, or as soon thereafter as feasible.

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9.2 Termination by Unilateral Action.

9.2.1 Written Notice. Either party may unilaterally terminate this entire Agreement at any time by giving the other party written notice, not less than 30 days prior to the desired termination date.

9.2.2 New Commitments. VA shall make no new commitments after receipt of a written termination notice from [the Company] and shall, to the extent feasible, cancel

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all outstanding commitments and contracts by the termination date.

9.3 Termination Costs. Within 90 days following termination of this Agreement, VA shall submit a statement of all costs incurred prior to the date of termination and for all termination costs for removal of abandoned property. Any unspent funds provided to VA by [the Company] shall be used to fund termination costs. In the event such funds are insufficient to cover all the termination costs, [the Company] agrees to promptly meet with VA to reach a settlement agreement regarding the payment of the remaining termination costs.

ARTICLE X. DISPUTES

10.1 Settlement. Any dispute arising under this Agreement which is not disposed of by agreement shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute.

10.2 Arbitration. If the signatories are unable to jointly resolve a dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted to arbitration in accordance with the Arbitration Rules of the American Arbitration Association then in effect, and the decision tendered by the arbitrators shall be binding as between the parties. Disputes pertaining to the scope, validity or ownership of any patent rights shall not be covered by this paragraph.

10.3 Continuation of Work. Pending the resolution of any dispute or claim pursuant to this Article, the parties agree that performance of all obligations shall be pursued diligently in accordance with the direction of the VA signatory named in paragraph 2.3.

ARTICLE XI. LIMITATION OF LIABILITY

11.1 Limitation of Liability. As determined under the provisions of the Federal Tort Claims Act (28 U.S.C. §§ 2671-2630), the United States (of which VA is a department) shall be liable for and hold harmless [The Company, its trustees, officers, employees and agents], from any and all claims, damages, losses, liabilities or expenses in connection with the performance of [for example, cancer therapy potential at the VA medical center location] on account of injuries to any person arising from or based on a negligent or wrongful act or omission of any VA employee while acting within the scope of the employee's office or employment, under circumstances where the United States, if a private person, would be liable to the injured person in accordance with the law of the place where the act or omission occurred.

11.2 No Warranty. Except as specifically stated in Article 8, VA makes no express or implied warranty as to any matter whatsoever, including the conditions of the research or any invention or product, whether tangible or intangible, made or developed under this Agreement, or the ownership,

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merchantability, or fitness for a particular purpose of the research or any invention or product.

11.3 Force Majeure. Neither party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to be unable to perform its obligations under this Agreement (and which it has been unable to overcome by the exercise of due diligence), including, but not limited to, flood, drought, earthquake, storm, fire, pestilence, lightning and other natural catastrophes, epidemic, war, riot, civic disturbance or disobedience, strikes, labor dispute, or

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failure, threat of failure, or sabotage of the VA facilities, or any order or injunction made by a court or public agency. In the event of the occurrence of such a force majeure event, the party unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

ARTICLE XII. MISCELLANEOUS

12.1 No Benefits. No member of or delegate to the United States Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

12.2 Governing Law. The construction validity, performance and effort of this Agreement for all purposes shall be governed by the laws applicable to the Government of the United States.

12.3 Entire Agreement. This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes any prior understanding or written or oral agreement relative to said matter.

12.4 Headings. Titles and headings of the sections and subsections of this Agreement are for the convenience of references only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

12.5 Waivers. None of the provisions of this Agreement shall be considered waived by any party hereto unless such waiver is given in writing to all other parties. The failure of any party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any party hereto.

12.6 Severability. The illegality or invalidity of any provisions of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement.

12.7 Amendments. If either party desires a modification in this Agreement, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by all the parties hereto by their representatives duly authorized to execute such amendment.

12.8 Assignment. Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party except that [the Company] may assign this Agreement to the successors or assignees of a substantial

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portion of [the Company's] business interests to which this Agreement directly pertains.

12.9 Notices. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative and shall be delivered by hand or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

a. If to [the Company]: [Name]
[Company, Inc.]
[Location]

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b. If to VA: [Name]
Laboratory Director
VA Medical Center
[location]

c. Any party may change such address by notice given to the other party in the manner set forth in paragraph 12.7.

12.10 Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners. VA shall maintain sole and exclusive control over its personnel and operations.

12.11 Use of Name or Endorsements

a. [The Company] shall not use the name of VA on any product or service which is directly or indirectly related to either this Agreement or any patent license or assignment agreement which implements this Agreement without the prior approval of VA.

b. By entering into this Agreement, VA does not directly or indirectly endorse any product or service provided, or to be provided, by [the Company], its successors, assignees, or licensees. [The Company] shall not in any way imply that this Agreement is an endorsement of any such product or service.

ARTICLE XIII. DURATION OF AGREEMENT AND EFFECTIVE DATE

13.1 Duration of Agreement. It is mutually recognized that the development program cannot be rigidly defined in advance, and that the contemplated time periods for completion of each phase are good faith guidelines subject to adjustment by mutual agreement, to fit circumstances as the development program proceeds. In no case will this Agreement extend beyond [date], unless it is revised in accordance with Article l2 of this Agreement.

13.2 Effective Date. This Agreement shall enter into force as of the date of the last signature of the parties.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as follows:

For [the Company]: _____

_____ _____

Date_____ _____

For the U.S. Government: _____

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Date: _____

STATEMENT OF WORK

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A MODEL LICENSE AGREEMENT

Effective (Date) 1987, the Director of the VA Medical Center, [location], as the representative of the United States of America (hereafter Licensor), and [the Company] agree as follows:

ARTICLE I. BACKGROUND

1.00 The United States of America is the owner by assignment recorded in the United States Patent and Trademark office on [date] (U.S. Patent Application No.) of the entire right, title and interest in and to the products and methods, described and claimed in the Licensed Patent, which pertain to the use of [List].

1.01 Under the authority of Section 11 of Public Law 99-502, 15 U.S.C. 3710a, Licensor has custody of the products and methods described and claimed in, and the right to issue licenses under the Licensed Patent.

1.02 Licensor desires the products and methods, claimed and described in the Licensed Patent, be brought to the Point of Practical Application in the shortest possible time and made available to the public, thereby serving the public interest and broadening the potential supply base for Licensor and other Government agencies.

1.03 Licensee desires to obtain an exclusive (or nonexclusive] license under the Licensed Patents for the purpose of developing [ ]

ARTICLE II. DEFINITIONS

2.00 Terms in this agreement (other than names of parties and article headings) which are set forth in italic and bold letters have the meanings established n the succeeding paragraphs of Article II.

2.01 Licensed Patents means U.S. Patent Application No. ( ) and U.S. Patent No. ( ) issued (Date), and such other foreign patent and patent applications as may be derived from the aforesaid U.S. Patent Application including any and all divisions, continuations in part, reissues, renewals or extensions thereof.

2.02 Licensed Products means any and all machines, articles of manufacture, products made by a process or compositions of matter as defined by the claims of Licensed Patents.

2.03 Licensed Methods means any and all products and methods, uses or processes which employ methods as claimed in the Licensed Patents.

2.04 Royalty-Base Products means any and all products which are employed to practice the Licensed Products and/or Methods.

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2.05 Licensed Area means the United States of America, its territories and possessions and any other country in which a Patent corresponding to the licensed U.S. patent has been filed and licensed.

2.06 Licensor's Representative means the General Counsel, Department of Veterans Affairs, Central Office, 810 Vermont Avenue, NW, Washington, DC, 20420.

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2.07 The Point of Practical Application means to develop the products and methods described and claimed in the Licensed Patents under such conditions as to establish that the products and methods are being utilized and that their benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms within [ ] years of the date of this Agreement, and to continue during the term of this Agreement to make the benefits of the products and methods reasonably accessible to the public.

2.08 Net Sales means the amount billed or invoiced on sales of any Royalty-Base Products or, in the event of disposal of any Royalty-Base Products other than as scrap prior to its shipment from its place of manufacture or other than by sales, the amount billed or invoiced for a like quantity and quality of Royalty-Base Products on or about the time of such disposal, less:

a. Customary trade, quantity or cash discounts including allowances or credits on account of retroactive price reductions and nonaffiliated brokers' or agents' commissions actually allowed and taken.

b. Amounts repaid or credited by reason of rejections or returns; and

c. Any freight or other transportation costs, insurance charges, duties, tariffs and all sales and excise taxes based directly on sales or turnover or delivery of material produced under this Agreement.

ARTICLE III. LICENSE GRANT

3.00 The Licensor grants to the Licensee an exclusive [or nonexclusive] license under the Licensed Patents to make, have made, use and/or sell the Licensed Products and Methods throughout the Licensed Area for the term set forth in Article X of this Agreement.

ARTICLE IV. ROYALTIES AND PAYMENTS

4.00 Licensee shall pay Licensor royalties at the rate of [ ] percent on Net Sales of all Royalty-Base Products. Should the license granted herein be converted to a nonexclusive license under the provisions of Article VIII, paragraph 8.02, Licensee shall pay royalties in accordance with the first sentence of this paragraph at the rate of [ ] percent.

4.01 Except for year 19__, specified in paragraph 2.01; in case the royalties paid do not aggregate a minimum of five thousand dollars ($5,000) for each calendar year during the life of this Agreement beginning with the second year in which sales subject to such royalties are made, the Licensee will within 60 days of the end of such year make up the deficiency of the royalties actually paid to such minimum sum. The minimum sum owed for the first year in which sales subject to such royalties are made will be prorated based on the month in which the first such sale is made.

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4.02 Royalties shall be payable in U.S. dollars, paid by check to VA.

4.03 Upon the execution of this Agreement, Licensee is to be credited for royalties, if any, in the year 19__.

4.04 Licensee shall pay royalties accrued for sales made subject to such royalties to include sales by its sublicensees not later than 60 days after each calendar half-year ending June 30th and December 31st.

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a. Licensee shall submit with its payment the written report required in Article V, paragraph 5.01, of this Agreement. If no royalties are due, the report shall so state.

b. Sales shall be considered to be made, for purposes of this paragraph and paragraph 4.01, when billed out, except that upon any termination of this Agreement, all shipments made on or prior to the day of such termination which have not been billed out prior thereto shall be considered as sold (and therefore subject to royalty).

c. Royalties paid on sales of Royalty-Base Products which are not accepted by the customer shall be credited to Licensee.

4.05 Licensee shall pay within 30 days from any termination of this Agreement royalties (including minimum royalties) accrued or accruable for payment at the time of any such termination.

4.06 Royalty payments not received by the due date shall be subject to interest charges computed at 10 percent per annum.

4.07 Transfer of Royalty-Base Products between Licensee and sublicensees shall not be deemed sales and shall not be included in computing Net Sales.

4.08 No royalty shall be payable under this Agreement for direct sales of Royalty Base Products by Licensee or its sublicensees to the U.S. Government or any of its agencies for governmental purposes.

ARTICLE V. REPORTS AND RECORDS

5.00 Licensee shall provide written annual progress reports within 60 days of end of each calendar year detailing its efforts, and the efforts of any sublicensee, to bring the products and methods licensed under this Agreement to the Point of Practical Application. No further annual progress reports will be required after notification of the first commercial sale of Royalty-Base Products unless otherwise requested by Licensor.

5.01 Concurrently with each payment of royalties as required in Article IV, paragraph 4.03, or at the time such payments are due although no royalties have accrued, Licensee shall submit a written report setting forth for the preceding 6-month period the amount of Royalty-Base Products made, used, sold or otherwise disposed of by Licensee and its sublicensees in the Licensed Area, the Net Sales thereof, and the amount of royalties due thereon. If no royalties are due Licensor for any report period, the report shall so state.

5.02 The reports required under Article V shall also be made within 30 days of the termination of this Agreement.

5.03 Licensee agrees to keep records showing the sales or other disposition of Royalty-Base Products sold or otherwise disposed of under the license granted

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in this Agreement in sufficient detail to enable the royalties payable hereunder by Licensee to be determined, and further agrees to permit its books and records to be examined from time to time to the extent necessary to verify the reports provided for in Article V, such examination to be made at the expense of the Licensor by any auditor appointed by Licensor who shall be acceptable to Licensee, or, at the option and expense of Licensee, by a certified public accountant appointed by Licensor.
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ARTICLE VI. SUBLICENSING RIGHTS

6.00 Licensee shall have the right under the Licensed Patents to grant sublicenses to others at royalty rates not less than those required to be paid by the first sentence of paragraph 4.00, Article IV,subject to the provisions of this Agreement and to the submission to and approval by Licensor's Representative, which approval shall not be unreasonably withheld. Any sublicense shall make reference to this Agreement including those rights retained by Licensor. A copy of any sublicense shall be furnished to Licensor's Representative promptly after its execution.

6.01 Royalties paid by a sublicensee to include any minimum royalties shall be shared equally by Licensee and Licensor.

6.02 Termination or conversion under Article VIII, paragraph 8.02, or any of the provisions of Article X of the license granted to Licensee in this Agreement shall terminate all sublicenses which may have been granted by Licensee, provided that any sublicensees may elect to continue its sublicense by advising Licensor in writing, within 60 days of the sublicensee's receipt of written notice of such termination or conversion, of its election, and of its agreement to assume in respect to Licensor all the obligations (including obligations for payment) contained in its sublicensing agreement with Licensee. Any sublicense granted by Licensee shall contain provisions corresponding to those of this paragraph respecting termination or conversion and the conditions of continuance of sublicensees.

6.03 Licensor reserves the right to require Licensee to grant sublicenses to responsible applicants on reasonable terms to the extent that the Licensed Patents are required for public use by Government regulations or when necessary to fulfill public health, welfare, or safety needs. Any decision by Licensor to require such a sublicense may be appealed by Licensee under the procedures set forth in Article XI.

ARTICLE VII. LICENSEE PERFORMANCE

7.00 Licensee shall expend reasonable efforts and resources to carry out the development and marketing of the licensed invention and to bring the products and methods, described and claimed in the Licensed Patents, to the Point of Practical Application.

7.01 After bringing the products and methods, described and claimed in the Licensed Patents, to the Point of Practical Application in the Licensed Area, Licensee agrees to make Licensed Products and Methods available to the public on reasonable terms during the term of this Agreement. Licensee shall promptly report discontinuance of its making the benefits of the products and methods reasonably accessible to the public.

7.02 Failure to comply with the terms of Article VIII shall be cause for modification or termination of this Agreement in accordance with the provisions of Article X.

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ARTICLE VIII. PATENT ENFORCEMENT

8.00 Licensor and Licensee shall notify each other promptly in writing of any infringement of Licensed Patents which becomes known to either of them. Licensee shall notify Licensor promptly of any action taken in accordance with Article VIII to eliminate such infringement.

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8.01 While and as long as its license under this Agreement remains exclusive, Licensee is authorized pursuant to the provisions of 35 U.S.C. chapter 29, or other statutes:

a. To bring suit in its own name or, if required by law, jointly with Licensor, at its own expense and on its own behalf, for infringement of the Licensed Patents;

b. In any such suit, to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and

c. To settle any claim or suit for infringement of Licensed Patents by granting the infringing party a sublicense under the provisions of Article VI of this Agreement. Any royalties received by Licensee pursuant to such a sublicense shall be shared with Licensor in accordance with Article VI, paragraph 6.01.

8.02 In the event the Licensor shall bring to the attention of Licensee any unlicensed infringement of the Licensed Patents, the Licensee shall, within 6 months, secure cessation of the infringement, or enter suit against the infringer, or provide Licensor with evidence of the pendency of a bona fide negotiation for the acceptance by the infringer of a sublicense under the Licensed Patents. If the Licensee fails to protect the patent as specified above, the license herein granted to the Licensee shall forthwith become nonexclusive, and Licensor shall therefore have the right to sue for the infringement at the Licensor's own expense, and to collect for its own use all damages, profits, and awards of whatever nature recoverable for such infringement.

8.03 Licensor and Licensee mutually agree to furnish technical and other necessary assistance to each other in conducting any litigation necessary to enforce the Licensed Patents against others. Expenses for such assistance will be paid by the party requesting such assistance.

ARTICLE IX. RESERVATION OF RIGHTS

9.00 The license granted in Article III of this Agreement shall be subject to the irrevocable, royalty-free right of the Government of the United States to practice and have practiced the products and methods described and claimed in Licensed Patents on behalf of the United States.

ARTICLE X. TERM AND TERMINATION

10.00 The term of this Agreement begins with its effective date as set forth in the heading paragraph located in front of Article I and, unless sooner terminated or otherwise modified as provided for in Article X, shall run, as to each of the Licensed Patents, for the full life of such patent. The life of the Licensed Patents shall also include any term of extension, if any, as provided by 35 U.S.C. chapter 14.

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10.01 The Licensor may modify or terminate this license, in whole or in part, if:

a. Licensee or any of its sublicenses fail to meet the obligations set forth in Article VII;

b. The Licensor determines that such action is necessary to meet requirements for

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public use specified by Federal regulations issued after the date of this Agreement and such requirements are not reasonably satisfied by the Licensee;

c. The Licensee has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by this Agreement;

d. The Licensee commits a substantial breach of covenant or agreement contained in this Agreement;

e. The Licensee defaults in making any payment or report required by this Agreement;

f. The Licensee is adjudged as bankrupt or has its assets placed in the hands of a receiver or makes any assignment or other accommodation for the benefit of creditors;

g. The Licensee or any of its sublicenses misuses the Licensed Patents.

10.02 Prior to any modification or termination of this Agreement, Licensor shall furnish Licensee and any sublicenses of record a written notice of intention to modify or terminate, and the Licensee and any notified sublicensee shall be allowed 30 days after the date of such notice of remedy any breach or default of any covenant or agreement of this Agreement or to show cause why this Agreement should not be modified or terminated.

10.03 The word "termination" and cognate words, such as "term" and "terminate," used in this Article X and elsewhere in this Agreement are to be read, except where the contrary is specifically indicated, as omitting from their effect the following rights and obligations, all of which survive any termination to the degree necessary to permit their complete fulfillment or discharge:

a. Licensee's obligation to supply a terminal report as specified in Article V, paragraph 5.02, of this Agreement.

b. Licensor's right to receive or recover and Licensee's obligation to pay royalties (including minimum royalties) accrued or accruable for payment at the time of any termination as specified in Article IV, paragraph 4.04, of this Agreement.

c. Licensee's obligation to maintain records and Licensor's right to conduct a final audit as provided in Article V of this Agreement.

d. Licenses, releases, and agreements of nonassertion running in favor of customers or transferees of Licensee in respect to Royalty-Base Products sold or transferred by Licensee prior to any termination and on which royalties shall have been paid as provided in Article IV.

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e. Any cause of action or claim of Licensor accrued or to accrue, because of any breach or default by Licensee.

10.04 In the event the termination of this Agreement or conversion of the license granted hereunder, any sublicense of record granted pursuant to this Agreement may, at sublicensee's option,, be converted to a license directly between sublicensee and Licensor in accordance with the provisions of Article VI herein.

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ARTICLE XI. GENERAL

11.00 This Agreement shall extend to any reissued patent which may be derived from the Licensed Patents, provided that Licensor has custody of the rights thereto and is able to grant a license without incurring liability to third parties; this Agreement shall not apply to the rights to any other invention, patent, or patent application.

11.01 This Agreement shall not be transferred or assigned by Licensee to any party other than to a successor or assignee of the entire business interest of Licensee relating to Royalty-Base Products without the approval of Licensor's Representative.

11.02 This Agreement does not confer any immunity from or defenses under the antitrust laws, and laws and regulations pertaining to or administered by the Food and Drug Administration, or the export laws, nor does it confer immunity from a charge of patent misuse. Furthermore, Licensee's or sublicensee's acquisition and exercise of rights hereunder are not immunized from the operation of any State or Federal law by reason of the source of the grant. This Agreement does not constitute an endorsement by Licensor of any Licensed Methods or Royalty-Base Products and Licensee shall not state or imply in any medium that such endorsement exists as the result of this Agreement.

11.03 Licensor makes no warranty, express or implied, regarding the patentability or validity of the Licensed Patents and no representations whatsoever with regard to the scope of the Licensed Patents or that the Licensed Patents may be exploited without infringing other patents.

11.04 Licensor agrees to maintain the Licensed Patents in force during the term of this Agreement by paying, when due, the fees required by 35 U.S.C. 41(b).

11.05 Licensor assumes no liability resulting from Licensee's exercise of its rights under this Agreement or from Licensor's exercise of its rights under this Agreement, including modification or termination thereof.

11.06 Licensee agrees that Royalty-Base Products used, sold, or otherwise disposed of in the Licensed Area by Licensee and its sublicensees will be manufactured substantially in the United States.

11.07 The decision of Licensor's Representative on any requirement, dispute, interpretation, modification, or termination of this Agreement shall be reduced to writing and a copy mailed or otherwise furnished to Licensee. Such decision shall be final, Provided, that Licensee may, within 30 days of receiving notice of such decision, submit a written appeal through Licensor's Representation to the Office of General Counsel (024), which VA appeal shall set forth in detail the decision being appealed and the basis of the appeal and may include appropriate supporting materials. Implementation of such decision shall be stayed pending a final resolution of such appeal. Pending such final

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resolution, Licensee shall proceed diligently with the performance of its obligations under this Agreement.

11.08 The parties shall notify each other of any changes in name, address, or business status, and any notice, payment or report required to be given under the provisions of this Agreement shall be considered duly given if mailed by first class mail, postage prepaid and addressed as follows:

a. If to Licensor: [Director]
[VA Medical Center]
[Location]

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b. If to Licensee: [Name/Title]
[Company]
[Location]

11.09 The interpretation and application of the provisions of this Agreement shall be governed by the laws of the United States as interpreted and applied by the Federal courts in the District of Columbia, United States of America.

11.10 This Agreement constitutes the entire understanding between the parties and neither party shall be obligated by any condition or representation other than those expressly stated herein or as ray be subsequently agreed to by the parties hereto in writing.

IN WITNESS THEREOF, each of the parties hereto has caused this Agreement to be executed in duplicate originals by its duly authorized officers or representatives.

FOR LICENSOR:

Director VA Medical Center	WITNESS
DATE	DATE

FOR LICENSEE:

WITNESS	WITNESS
DATE	DATE